



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.

08/989,896

Examiner

Saunders David

Applicant(s)

GEHRMANN ET AL.

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 November 2000 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either a timely filed amendment which places the application in condition for allowance or a Notice of Appeal. Alternatively, applicant may obtain further examination by timely filling a request for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d).

PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 707.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136 (a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked.

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (see NOTE below);
- (b) ☒ they raise the issue of new matter. (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s): _____.
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached note.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☐ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1-13 and 25-33.
- Claim(s) withdrawn from consideration: 14-22.
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
11. ☐ Other: _____.

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The following correction has been entered in the previous Office action in red ink and dated and initialed by the examiner:

At page 2, third line from bottom, changed "2" to -3--.

The proposed amendment to claim 1 raises an issue of new matter, since the claim would recite "...the compound has a bivalent or multivalent structure". Applicant has urged that the para. Spanning pages 5-6 supports the change. This portion of the specification, however, only discloses compounds which are dimers or tetramers (2 and 4 binding regions). The proposed recitation of multivalent would encompass molecular forms (e.g. trimers) not supported by the disclosure. The examiner notes that the recitation that "...the antigen binding region has a bivalent or multivalent structure" (as in the twice-amended version presented on 5/11/00) is supported by specification page 2.

The amendments to claims 2 and 29 would be separately enterable.

The amendments to claims 3 and 30 would appear to be enterable; however, the examiner can make no decisive judgement, until claim 1 has been amended in a manner that raises no new issues.

The urgings regarding the 103 rejection are unconvincing. These merely present conclusionary statements that sFv regions to tumor antigens and pro-drug activating enzymes would not have been expected to work together in a fusion protein. Applicant's urgings regarding Huston et al's teachings of the unpredictability of linker technology are unconvincing since Huston et al teach that "Although data are limited,

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the literature referenced in Table I suggests that some latitude exists in the design of linkers capable of producing functional sFv proteins. Linker fusion between V domains need not, in principle, compromise the folding of an sFv binding site." Therefore, one would have expected a reasonable degree of success in combining the teachings of the cited prior art to achieve a fusion protein having a functional sFv region capable of binding a tumor antigen and having a functional pro-drug activating enzyme region.

Any inquiry concerning this communication should be directed to David A.

Saunders at telephone number 703-308-3976.

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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